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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,975	03/16/2004	Robert S. Biscup	MEDR 200001US01	2554
27885	7590	02/17/2010		
FAY SHARPE LLP 1228 Euclid Avenue, 5th Floor The Halle Building Cleveland, OH 44115			EXAMINER RAMANA, ANURADHA	
			ART UNIT 3775	PAPER NUMBER
			MAIL DATE 02/17/2010	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/801,975	<b>Applicant(s)</b> BISCUP ET AL.	
	<b>Examiner</b> Anu Ramana	<b>Art Unit</b> 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,2,5,7-51,78,80 and 84-99 is/are pending in the application.
- 4a) Of the above claim(s) 9-11,13,38, and 40-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,7,8,12,14-37,39,78,80 and 84-99 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 5, 7-8, 12, 14-37, 39, 78, 80, and 84-97 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the interchangeable use of "expandable component" and "expanded component" is confusing.

Further, in line 8, the recitation "a greater perimeter" is incomplete since it is not clear what dimension the "perimeter" is being compared to.

In claim 78, the recitation "designed increasing in surface area and having a greater perimeter" renders the claim vague and indefinite since the recitation is incomplete and it is unclear what dimension the "perimeter" is being compared to.

In claim 80, the recitation "greater perimeter" renders the claim vague and indefinite since it is unclear what dimension the "perimeter" is being compared to.

In claim 84, the recitation "greater perimeter" renders the claim vague and indefinite since it is unclear what dimension the "perimeter" is being compared to.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 5, 7-8, 12, 15, 17-22, 24-37, 39, and 98 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuslich (US 5,571,189).

Kuslich discloses a prosthetic implant including: a substantially spherical bag 40 made of a material impregnated with a biologically active material such as ground up bone graft, i.e., unexpandable component, making the top and bottom portions of the implant substantially non-expandable; and an inflatable band or “expandable component” or “stabilizer” 42 having a disc shape (Figs. 9 and 13, col. 6, lines 57-67, cols. 7-9 and col. 10, lines 1-9).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14, 16, 22, 23, 93-95 and 99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslich (US 5,571,189).

Regarding claims 14, 16, and 93-95, although Kuslich does not disclose the relative dimensions of the band with respect to the balloon, it has been held that, where the only difference between the prior art and the claims is the recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than a prior art device, the claimed device is not patentably distinct from the prior art device. *Gardner v. TEC Systems, Inc.*, 725 F. 2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984).

Regarding claims 22, 23 and 99, although Kuslich does not specifically disclose the expandable component to have a tapered edge, it would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the Kuslich band with a shape having a tapered edge, since applicant has not disclosed that this solves any stated problem or is anything more than one of numerous shapes or configurations a person of ordinary skill in the art would find obvious for the purpose of providing a stabilizer element. In re Dailey and Eilers, 149 USPQ 47 (1966).

### ***Response to Arguments***

Applicant's arguments have been fully considered but are not persuasive with respect to the rejections of claims 1, 2, 7-8, 21 and 22 for the following reasons.

With respect to claim 1, Kuslich discloses a substantially spherical or ellipsoidal body with an equatorial band 42 formed of multiple layers of fabric, making the band expandable or capable of being expanded (col. 10, lines 7-9). It is the examiner's position that when the Kuslich implant 40 is filled, the band also expands, although to a lesser extent than the implant, forming a stabilizer having a perimeter greater than a perimeter of the top and bottom portions of implant 40 when implant 40 is completely filled.

With respect to claim 2, the recitation "top and bottom portions of said substantially spherical or ellipsoidal body are substantially non-expandable" is met by Kuslich as discussed in this office action.

Regarding claims 7 and 8, the recitation "expandable radially outwardly" or "expands radially outwardly" is met by equatorial band 42 since it is capable of expanding radially when implant 40 is filled.

### ***Allowable Subject Matter***

Claims 78, 80, 84-92, 96 and 97 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached at (571) 272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3775

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR

February 10, 2010

/Anu Ramana/

Primary Examiner, Art Unit 3775